IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI SOUTHWESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ROBERT L. CARTER, M.D.
[DOB: 12-25-1940],

Defendant.

Case No. 15-03038-01-CR-S-DPR

COUNT 1
18 U.S.C. § 2
21 U.S.C. §§ 331(c) and 333(a)(1)
NMT 1 Year Imprisonment
NMT $100,000 Fine
NMT 1 Year Supervised Release
Class A Misdemeanor

FORFEITURE ALLEGATION
18 U.S.C. § 982(a)(7)
21 U.S.C. § 853(p)
18 U.S.C. § 982(b)

$25 Mandatory Penalty
Assessment-Each Count

INFORMATION

THE UNITED STATES ATTORNEY STATES:

INTRODUCTION AND BACKGROUND

1. Robert L. Carter, M.D., was the President, sole Director, and medical practitioner of Robert L. Carter, M.D., P.C., a Domestic Professional Corporation in good standing in Joplin, Missouri since its inception in October 23, 1991 and continuing to its dissolution on or about April 2, 2012.

2. As a Medical Oncologist, Dr. Carter, through his medical practice (hereinafter, "the practice"), provided care and treatment for patients with cancer and blood diseases.

3. As part of the Dr. Carter's treatment of patients for cancer and other diseases, the practice purchased prescription drugs, to include chemotherapy drugs, which were prescribed by Dr. Carter and were administered and dispensed through the practice. Reimbursement for the drugs

and their administration was sought from the Medicare, Medicaid, and Tricare programs as well as other private health care benefit programs.

4. Quality Specialty Products (hereinafter, "QSP") was a business with a reported address in Winnipeg, Manitoba, Canada, offering for sale to physicians and other health care providers in the United States drugs which had been obtained from foreign sources and which had not been approved by the U.S. Food and Drug Administration for distribution or use in the United States.

5. The United States Food and Drug Administration ("FDA") is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq.* ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce and foreign commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforces statutes which require that drugs bear labels and labeling that enable health care providers and consumers to use them in a safe manner. 21 U.S.C. §§ 352(f) and 353(b)(4)(A).

6. Under the FDCA, drugs include: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; articles intended to affect the structure or any function of the body of man; and "biological products" applicable to the prevention, treatment, or cure of a disease or condition of human beings. 21 U.S.C. § 321(g)(1)(B) and (C); 42 U.S.C. § 262(i).

7. Under the FDCA, a "label" is a display or written, printed, or graphic matter upon the immediate container of any article, and "labeling" is all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(k) and (m).

8. Under the FDCA, a drug is deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it is not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug is also deemed to be a prescription drug if a new drug application approved by the FDA limits the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355.

9. Between April 2010 and May 2011, Dr. Carter purchased the drugs listed below from QSP and received them in interstate commerce at the practice in Joplin, Missouri. The drugs, using the names under which the drugs are marketed in the United States, are used primarily to treat individuals with cancer, and are often "infused" into cancer patients intravenously, meaning the purity and efficacy of these prescription drugs is very important for patients. All of these drugs are "prescription drugs" pursuant to 21 U.S.C. § 353(b)(1) because of their toxicity or other potentiality for harmful effect, and could lawfully be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs:

Palonosetron Injection (the FDA-approved version is labeled "ALOXI®")

Bevacizumab Injection (the FDA-approved version is labeled "AVASTIN®")

Oxaliplatin Injection (the FDA-approved version is labeled "ELOXATIN®")

Fulvestrant Injection (the FDA-approved version is labeled "FASLODEX®")

Gemcitabine Hydrochloride (the FDA-approved version is labeled "GEMZAR®")

Trastuzumab Injection (the FDA-approved version is labeled "HERCEPTIN®")

Pegfilgrastim Injection (the FDA-approved version is labeled "NEULASTA®")

Filgrastim Injection (the FDA-approved version is labeled "NEUPOGEN®")

Docetaxel Injection (the FDA-approved version is labeled "TAXOTERE®")

Bortezomib (the FDA-approved version is labeled "VELCADE®")

Zoledronic Acid Injection (the FDA-approved version is labeled "ZOMETA®")

Ibandronate (the FDA-approved version is labeled "BONIVA®")

Topotecan Injection (the FDA-approved version is labeled "HYCAMTIN®")

Azacitidine Injection (the FDA-approved version is labeled "VIDAZA®")

10. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug is "misbranded" unless the labeling bears adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5. All words, statements, and other information required to appear on drug labeling by the FDCA must be in the English language, unless the drug is solely distributed in Puerto Rico or a United States territory. 21 C.F.R. § 201.15(c)(1). A drug is "misbranded" if it is a prescription drug and, prior to dispensing, its label fails to bear the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A); 21 C.F.R. § 201.100(b)(1).

11. The labeling for the prescription drugs that Dr. Carter purchased from QSP between April 2010 and May 2011 and received by the practice in interstate commerce were different from the versions of the drugs the FDA had approved for sale in the United States. Among other things, those prescription drugs did not have labels bearing the symbol "Rx only" and their labeling failed to bear adequate directions for use. The labeling for some of the drugs was in one or more foreign languages and some of the prescription drugs lacked mixing and use instructions in the English language. Moreover, some of the prescription drugs were labeled with names that were

different than the names of the FDA–approved drugs. For example, Dr. Carter received: (1) "Altuzan" instead of "Avastin"; (2) "Mabthera" instead of "Rituxan"; and (3) "Neulastim" instead of "Neulasta."

COUNT 1

12. Paragraphs 1 through 11 of the General Allegations of this Information are re-alleged and incorporated by reference as though fully set forth herein.

Between April 2010, and May 2011, said dates being approximate, in Jasper County, in the Western District of Missouri, and elsewhere, the defendant, **ROBERT L. CARTER, M.D.**, received and caused to be received in interstate commerce misbranded prescription drugs – specifically, 211 vials of 400mg/16ml Altuzan and 196 vials of 100mg/4ml Altuzan – that were misbranded within the meaning of (i) 21 U.S.C. § 353(b)(4)(A) in that their labels failed to bear the symbol "Rx only"; and (ii) 21 U.S.C. § 352(f)(1) in that their labeling failed to bear adequate directions for use, and delivered and caused the delivery and proffered delivery of such drugs for pay or otherwise;

All in violation of Title 21, United States Code, Section 331(c) and 333(a)(1); 18 U.S.C. § 2.

FORFEITURE ALLEGATION

The United States Attorney re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 11 and Count 1 of this Information for the purpose of alleging forfeiture to the United States of America pursuant to 18 U.S.C. § 982(a)(7).

Upon conviction of any offense in violation of 21 U.S.C. § 331, the defendant, **ROBERT L. CARTER, M.D.**, shall forfeit to the United States of America pursuant to 18 U.S.C. § 982(a)(7), all property, real and personal, constituting, or derived from, proceeds traceable to the

offense, directly or indirectly, as a result of the violations of law set forth in Count 1 of this Information, including but not limited to the following property:

MONEY JUDGMENT

1) A sum of money of at least **$1,200,000.00** in United States currency, as that amount constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

SUBSTITUTE ASSETS

If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

a. cannot be located upon exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States of America, pursuant to 21 U.S.C. § 853(p), and 18 U.S.C. § 982(b), to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described above.

Respectfully submitted,
TAMMY DICKINSON
United States Attorney

Abram McGuff, II
Assistant United States Attorney

DATED: 3-30-2015
Springfield, Missouri

ORIGINAL